

Application Number 10/731,867

Amendment dated June 27, 2006

Responsive to Office Action mailed February 27, 2006

**REMARKS**

This Amendment is submitted with a Request for Continued Examination, and is responsive to the Final Office Action dated February 27, 2006. Applicant has amended claims 1 and 23, canceled claim 25, and added new claims 30 and 31. Claims 1-24 and 26-31 are pending.

**Amendments to the Specification**

Applicant has amended paragraphs [0050], [0061] and [0069] to briefly discuss the horizontal distribution of module housings at respective locations of an overmold, and the separate encapsulation of such housings by an overmold, depicted in FIGS. 3, 7A, 7B, 10A and 10B. By these amendments, Applicant provides additional support in the written description for the amendment to independent claim 1, as well as the limitations recited in new claim 31. These amendments are fully supported by FIGS. 3, 7A, 7B, 10A and 10B as originally filed and, therefore, add no new matter.

**Claim Rejections Under 35 U.S.C. § 102**

In the Final Office Action, the Examiner rejected claims 1-2, 4-6, 10-11, 13-15, 17-18 and 22 under 35 U.S.C. § 102(b) as being anticipated by US 6,128,538 to Fischell et al. (Fischell). The Examiner also rejected claims 1-6, 11 and 22 under 35 U.S.C. § 102(e) as being anticipated by US 6,788,974 to Bardy et al. (Bardy).

Applicant respectfully traverses these rejections to the extent such rejection may be considered applicable to the amended claims. The applied references to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102, and provide no teaching that would have suggested the desirability of modification to include such features.

For example, the applied references fail to disclose or suggest an implantable medical device comprising a plurality of housings and an overmold that at least partially encapsulates each of the housings, wherein the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold, as recited by Applicant's independent claim 1, as amended.

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In contrast to these requirements of amended claim 1, Fischell depicts a control module 620 comprising an electronics module 626, and a battery 625 that is stacked on top of the electronics module 626.<sup>1</sup> In, in rejecting claim 1 as previously presented, the Office Action asserted that the metal shell 621 and top plate 624 depicted in FIG. 21 of Fischell form an overmold that encapsulates both the electronics module 626 and the battery 625. However, Fischell indicates that top plate 624 is a part of the battery 625, rather than part of a separate overmold that encapsulates both the battery and the electronics module.<sup>2</sup> Moreover, even accepting the Office Action's erroneous interpretation of FIG. 21 of Fischell, the "overmold" comprising the shell 621 and top plate 624 does not separately encapsulate the electronics module 626 and the battery 625. Accordingly, Fischell would not have suggested housings horizontally distributed at respective locations of an overmold, and separately encapsulated by the overmold, as required by amended independent claim 1.

Bardy also fails to suggest these requirements of amended claim 1. Contrary to these requirements, Bardy teaches that the battery supply, capacitor and operational circuitry of a US-ICD is packaged within a single housing, which is in turn located within the US-ICD canister at a single location and referred to as the core member.<sup>3</sup> Accordingly, Bardy does not suggest a plurality of housings horizontally distributed at respective locations of an overmold, and separately encapsulated by the overmold, as required by amended independent claim 1.

Fischell and Bardy also fail to disclose a surface of an overmold that is concave along two axes, as required by claim 2, or a surface of a housing that is concave along two axes, as required by claim 14. The figures of Fischell and Bardy cited in the Office Action do not provide any indication that the depicted devices are concave along more than a single axis. In fact, the axial cross-section depicted in FIG. 21 of Fischell, by definition, only indicates that the Fischell device is concave along the single axis of the cross-section. Furthermore, the portions of the Fischell and Bardy descriptions cited in the Office Action are do not in any way indicate that the described devices are concave along more than one axis. The cited portions of the Fischell disclosure are not even related to concavity, while the cited portions of Bardy merely indicate

<sup>1</sup> Fischell, FIG. 21.

<sup>2</sup> Fischell, col. 29, ll. 43-45.

<sup>3</sup> Bardy, col. 13, ln. 56 - col. 14, ln. 16.

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that the described devices may have different curvatures. "Different curvatures," as mentioned in *Bardy*, means different degrees of curvature along the same axis, rather than concavity along more than one axis, as required by Applicant's claims.<sup>4</sup>

As another example, Fischell fails to disclose or suggest a battery with a wound coil construction, as required by claim 15. The coil 635 of the Fischell system, cited in the Office Action, is not a battery. The coil 635 is an entirely separate element from the battery 624 of the Fischell system. Coil 635 is used for transcutaneous communication and energy transfer, and bears no relationship to the structure of a battery. The disclosure of the coil 635 would not have suggested a battery with a wound coil construction, as required by claim 15, to a person of ordinary skill in the art.

The applied references fails to disclose each and every limitation set forth in claims 1-2, 4-6, 10-11, 13-15, 17-18 and 22. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of these claims under 35 U.S.C. § 102. Withdrawal of these rejections is respectfully requested.

#### **Claim Rejections Under 35 U.S.C. § 103**

In the Final Office Action, the Examiner rejected claims 7-9, 19-21 and 23-29 under 35 U.S.C. § 103(a) as being unpatentable over Fischell, and rejected claims 7-9 and 23-29 under 35 U.S.C. § 103(a) as being unpatentable over *Bardy*. The Examiner also rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of US 6,308,101 to Faltys et al. (*Faltys*), and claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of US 3,358,281 to Berrang et al. (*Berrang*).

Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that neither *Faltys* nor *Berrang* provides any teaching that would have suggested modification of the Fischell or *Bardy* devices to include housings horizontally

<sup>4</sup> *Bardy*, col. 25, ll. 14-65.

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distributed at respective locations of an overmold, and separately encapsulated by the overmold, as required by amended independent claim 1.

Further, with respect to claims 19 and 20, Fischell fails to disclose or suggest that the battery 625 or control module 626 conforms to an arc, wherein the radius of the arc is within a range from 4.5 to 9.5 centimeters, as required by claim 19, or approximately equal to 7 centimeters, as required by claim 20. The Office Action acknowledged that Fischell fails to disclose or suggest these requirements of claims 19 and 20. Nonetheless, relying on holdings of the Federal Circuit, the Office Action argued that it would have been obvious for one of ordinary skill to make the modules described in Fischell conform to such arcs because discovering optimum ranges or values of result effective variables involves only routine skill in the art.

However, "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."<sup>5</sup> The holdings on which the Examiner relies are based on optimization of a value or range disclosed in the prior art that is different from the claimed range or value.<sup>6</sup> Fischell does not even discuss arcs or radii of curvature, much less provide a range or value for such measurements that one of ordinary skill could optimize. Accordingly, the holdings relied on in the Office Action are inapplicable to the rejection of claims 19 and 20 as unpatentable over Fischell.

The same reasoning applies to overcome the rejection of claims 23 and 24, which recite similar radius of curvature limitations, as being unpatentable over Fischell. Furthermore, as amended, independent claim 23 requires that the surface of the recited housing is concave along at least two axes. As discussed above with reference to claims 2 and 14, neither Fischell nor Bardy discloses a surface that is concave along at least two axes, as required by amended claim 23.

Additionally, with respect to claims 28 and 29, the Office Action acknowledges that none of the applied references discloses or suggests two metallic housings, as required by claim 28, or two hermetic housings formed of titanium or stainless steel, as required by claim 29. Nonetheless, the Office Action argued that modification of the Fischell and Bardy devices to

<sup>5</sup> *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (emphasis added); *see also* MPEP 2144.05.

<sup>6</sup> *See* MPEP 2144.05.

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include module housings in accordance with the requirements claims 28 and 29 would have been a matter of obvious design choice. This conclusion lacks any evidentiary basis, and is legally impermissible.

Fischell and Bardy teach components, such as capacitors, operational circuitry, and an electronics module, which are already located within a housing. The Examiner has interpreted these housings to be overmolds within the meaning of Applicant's claims. The Office Action has cited no teaching in the prior art of using an additional metallic, stainless steel, or titanium housing, within the "overmold" housing, to individually house such components. The Office Action has cited no evidence that a person of ordinary skill in the art would have considered it obvious to, for example, house a circuit board within a metallic housing, and then place the circuit board and housing, along with other components, within a larger implantable medical device housing, e.g., as set forth in claims 28 and 29.

Lacking any evidence supporting the purported obviousness of the proposed modification, the Office Action relied on legally improper assertions of "design choice." Such unsupported assertions are contrary to clear Federal Circuit precedent, which holds that a finding of obviousness must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.<sup>7</sup> Consequently, unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill to include two housings with the Fischell and Bardy devices that meet the requirements of claims 28 and 29, the claims should be allowed.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 7-9, 12, 16, 19-21 and 23-29 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

<sup>7</sup> *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002) (emphasis added).

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### **Rejection for Obviousness-type Double Patenting**

The Examiner provisionally rejected claims 1-29 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over: claims 1-9, 11-15, 18, 20-30, 35-39, 51 and 53-55 of copending Application No. 10/731,869; and claims 1-8, 12-14, 18-22, 31-35, 39-43 and 45-49 of copending Application No. 10/730,873. Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

### **New Claims**

Applicant has added claims 30 and 31 to the pending application. No new matter has been added by the new claims. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

For example, for at least the reasons discussed above with reference to claims 19, 20, 23, 28 and 29, the references fail to disclose or suggest an implantable medical device comprising a plurality of metallic housings, and a flexible overmold that at least partially encapsulates the plurality of metallic housings, wherein a surface of the overmold is concave such that it conforms to an arc with a radius within a range from 4.5 to 9.5 centimeters, as recited by new independent claim 30. Further, for at least the reasons discussed above with reference to amended independent claim 1, the applied references fail to disclose or suggest that the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold, as recited by new claim 31.

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**CONCLUSION**

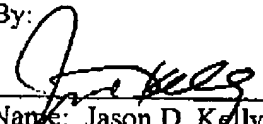
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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6/27/06

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